



PTO/SB/08a (08-03)

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 11

Complete If Known

Application Number	10/775481
Filing Date	February 10, 2004
First Named Inventor	Scott Waldman
Art Unit	1842
Examiner Name	Catherine Joyce
Attorney Docket Number	TJU0016-100 (WAL_SCO.008/CGG)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication/Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
/PR/	AA	US-5,518,888	05-21-1996	Scott A Waldmann et al.	
/PR/	AB	US-5,879,656	03-09-1999	Scott A Waldmann et al.	
/PR/	AC	US-6,060,037	05-09-2000	Scott A Waldmann et al.	
/PR/	AD	US-6,268,159	07-31-2001	Scott A Waldmann et al.	
/PR/	AE	US-5,601,990	02-11-1997	Scott A Waldmann et al.	
/PR/	AF	US-5,731,159	03-24-1998	Scott A Waldmann et al.	
/PR/	AG	US-5,928,873	07-27-1999	Scott A Waldmann et al.	
/PR/	AH	US-5,962,220	10-05-1999	Scott A Waldmann et al.	
/PR/	AI	US-6,087,109	07-11-2000	Scott A Waldmann et al.	
/PR/	AJ	US-6,767,704	07-27-2004	Scott A Waldmann et al.	
/PR/	AK	US-5,530,101	06-25-1996	Cary L. Queen et al.	
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/PR/	AO	US-5,338,665	08-16-0994	Schatz et al.	
/PR/	AP	US-5,395,750	03-07-1995	Dillon et al.	
/PR/	AQ	US-5,223,409	6-29-1993	Ladner et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date/Filing Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	† ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
/PR/	AR	WO9742220	11-13-1997	Thomas Jefferson University		
/PR/	AS	WO9511694	05-04-1995	Thomas Jefferson University		
/PR/	AT	WO9742506	11-13-1997	Thomas Jefferson University		

Examiner Signature	/Peter Reddig/	Date Considered	10/06/2007
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Substitute for form 1449A/PTO <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;">(Use as many sheets as necessary)</p>		Complete If Known <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>10/775481</td> </tr> <tr> <td>Filing Date</td> <td>February 10, 2004</td> </tr> <tr> <td>First Named Inventor</td> <td>Scott Waldman</td> </tr> <tr> <td>Art Unit</td> <td>1842</td> </tr> <tr> <td>Examiner Name</td> <td>Catherine Joyca</td> </tr> <tr> <td>Attorney Docket Number</td> <td>TJU0018-100 (WAL_SCO.008/CGG)</td> </tr> </table>		Application Number	10/775481	Filing Date	February 10, 2004	First Named Inventor	Scott Waldman	Art Unit	1842	Examiner Name	Catherine Joyca	Attorney Docket Number	TJU0018-100 (WAL_SCO.008/CGG)
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/PR/	AU	US-5,366,862	11-22-1994	Venton et al.	
/PR/	AV	US-5,340,474	08-23-1994	Kauvar et al.	
/PR/	AW	US-5,133,866	07-28-1992	Lawrence M. Kauvar et al.	
/PR/	AX	US-4,963,263	10-16-1990	Lawrence M. Kauvar et al.	
/PR/	AY	US-5,217,869	06-08-1993	Lawrence M. Kauvar et al.	
/PR/	AZ	US-5,405,783	04-11-1995	Pirrung et al.	
/PR/	BA	US-5,143,854	09-01-1992	Pirrung et al.	
/PR/	BB	US-5,384,261	01-24-1995	Winkler et al.	
/PR/	BC	US-5,221,736	06-22-1993	Coolidge et al.	
/PR/	BD	US-5,412,087	05-02-1995	McGall et al.	
/PR/	BE	US-5,324,483	06-28-1994	Cody et al.	
/PR/	BF	US-5,252,743	10-12-1993	Barret et al.	
/PR/	BG	US-5,424,186	06-13-1995	Foder et al.	
/PR/	BH	US-5,420,328	05-30-1995	Campbell et al.	
/PR/	BI	US-5,288,514	02-22-1994	Ellman et al.	
/PR/	BJ	US-4,601,896	07-22-1986	Mark Nugent et al.	
/PR/	BK	US-4,729,893	03-08-1988	Robert L. Letcher et al.	

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Art Unit	1642
Examiner Name	Catherine Joyce
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(Use as many sheets as necessary)

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Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/775481
		Filing Date	February 10, 2004
		First Named Inventor	Scott Waldman
		Art Unit	1642
		Examiner Name	Catherine Joyce
		Attorney Docket Number	TJU0016-100 (WAL_SCO.008/CGG)
Sheet	4	of	11

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/PR/	BP	Ames, J. B. et al., "Three-dimensional structure of guanylyl cyclase activating protein-2, a calcium-sensitive modulator of photoreceptor guanylyl cyclases," <i>J. Biol. Chem.</i> , (1999), 274, 19329-19337.	
/PR/	BQ	Andric et al. "Dependence of soluble guanylyl cyclase activity on calcium signaling in pituitary cells," <i>J. Biol. Chem.</i> (2001), 276, 844-849	
/PR/	BR	Berridge, M. J. et al., "Calcium—a life and death signal," <i>Nature</i> (1998), 395, 645-648.	
/PR/	BS	Bhattacharya, J. et al., "Rise of intracellular free calcium levels with activation of inositol triphosphate in a human colonic carcinoma cell line (COLO 205) by heat-stable enterotoxin of <i>Escherichia coli</i> ," <i>Biochim. Biophys. Acta</i> (1998), 1403, 14	
/PR/	BT	Biel et al., "Cyclic nucleotide-gated channels—mediators of NO:cGMP-regulated processes," <i>Naunyn Schmiedeberg's Arch. Pharmacol.</i> (1998), 358, 140-144	
/PR/	BU	Birkenkamp-Demtröder, K. et al., "Gene expression in colorectal cancer," <i>Cancer Res.</i> (2002), 62, 4352-4363	
/PR/	BV	Blanchard R.K. et al., "Upregulation of rat intestinal uroguanylin mRNA by dietary zinc restriction," <i>Am. J. Physiol.</i> (1997) 272 (5Pt 1) G972-978	
	BW	Bodanszky et al., <i>Peptide Synthesis</i>, (1976) John Wiley & Sons, 2d Ed	
/PR/	BX	Brenner et al., "Encoded combinatorial chemistry," <i>Proc. Natl. Acad. Sci. USA</i> (June 1992), 89:5381-5383.	
/PR/	BY	Briskey, E. N. et al., "Colorectal cancer: update on recent advances and their impact on screening protocols," <i>J. Natl. Med. Assoc.</i> (2000), 92(5), 222-230.	
/PR/	BZ	Buset, M. et al., "Inhibition of human colonic epithelial cell proliferation in vivo and in vitro by calcium," <i>Cancer Res.</i> (1986), 46, 5426-5430	

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Sheet 5 of 11

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Application Number	10775481
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First Named Inventor	Scott Waldman
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Examiner Name	Catherine Joyce
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/PR/	CA	Butt, E., "(Rp)-8-pCPT-cGMPS, a novel cGMP-dependent protein kinase inhibitor," <i>Eur. J. Pharmacol.</i> (1994), 269(2), 265-268.	
/PR/	CB	Carrithers et al., "Guanylyl cyclase C is a selective marker for metastatic colorectal tumors in human extraintestinal tissues," <i>Proc Natl Acad Sci USA</i> (1996) 93(25):14827-32.	
	CC	Centers for Disease Control and Prevention. (2001) in <u>Health Information for International Travel 1999-2000</u> (Department of Health and Human Services, Atlanta).	
/PR/	CD	Chan et al., "Amino acid sequence of heat-stable enterotoxin produced by <i>Escherichia coli</i> pathogenic for man," <i>J. Biol. Chem.</i> (1981), 256(15):7744-6.	
/PR/	CE	Chao, A. C. et al., "Activation of intestinal CFTR Cl ⁻ channel by heat-stable enterotoxin and guanylin via cAMP-dependent protein kinase," <i>EMBO J.</i> (1994) 13(5):1065-72.	
/PR/	CF	Cohen et al., "Guanylin mRNA expression in human intestine and colorectal adenocarcinoma," <i>Lab. Invest.</i> (1998), 78(1), 101-108.	
/PR/	CG	Cull M.G. et al., "Screening for receptor ligands using large libraries of peptides linked to the C terminus of the lac repressor," <i>Proc. Natl. Acad. Sci. USA</i> (March 1992), 89:1865-1869.	
/PR/	CH	Currie, M.G. et al., "Guanylin: an endogenous activator of intestinal guanylate cyclase," <i>Proc. natl. Acad. Sci. USA</i> (1992) 89:947-951.	
/PR/	CI	Devor, D. C. et al., "Modulation of K ⁺ channels by arachidonic acid in T84 cells. I. Inhibition of the Ca(2+)-dependent K ⁺ channel," <i>Am. J. Physiol.</i> (1998), 274, C138-C148.	
/PR/	CJ	Dostmann, W. R. et al., "(RP)-cAMPS inhibits the cAMP-dependent protein kinase by blocking the cAMP-induced conformational transition," <i>FEBS Lett.</i> (1995), 375(3), 231-234.	
/PR/	CK	Dayhoff, M.O. et al., "A model of evolutionary change in proteins" in <i>Atlas of Protein Sequence and Structure</i> , Nat. Biomed. Res. Foundation, Washington D.C. (1978), Vol. 5, supp. 3, chapter 22, 345-352.	

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/PR/	CL	Dzeja, C. et al., "Ca ²⁺ permeation in cyclic nucleotide-gated channels," <i>EMBO J.</i> 1999 Jan 4;18(1):131-44. 18, 131144.	
/PR/	CM	Fodor, S. P. A. et al., "Light-directed, spatially addressable parallel chemical synthesis," <i>Science</i> Vol 251, Issue 4995, 767-773 (Feb. 15, 1991).	
	CN	Ferlay, J., (2001) in <i>GLOBOCAN 2000: Cancer Incidence, Mortality and Prevalence Worldwide</i> , Version 1.0 (International Agency for Research on Cancer, Lyon).	
/PR/	CO	Fischer, T. A et al. "Activation of cGMP-dependent protein kinase I β inhibits interleukin 2 release and proliferation of T cell receptor-stimulated human peripheral T cells," 20 U., Sopper, S., & Lohmann, S. M. (2001). <i>J. Biol. Chem.</i> 276, 5967-5974	
/PR/	CP	Forte L. R., "Guanylin regulatory peptides: structures, biological activities mediated by cyclic GMP and pathobiology," <i>Regul. Pept.</i> (1999) May 31;81(1-3):25-39.	
/PR/	CQ	Fukumoto, S. et al., "Distinct role of cAMP and cGMP in the cell cycle control of vascular smooth muscle cells: cGMP delays cell cycle transition through suppression of cyclin D1 and cyclin-dependent kinase 4 activation," <i>Circ. Res.</i> (1999) 85(11), 985-991.	
/PR/	CR	Gadbois, D. M. et al. "Multiple kinase arrest points in the G1 phase of nontransformed mammalian cells are absent in transformed cells," <i>Proc. Natl. Acad. Sci. USA</i> (1992), 89(18), 8626-8630	
	CS	Cenarro, Alfonso, ed. <i>Remington's Pharmaceutical Sciences</i>, 16th Edition, 1990, Mack Publishing Co., Easton PA.	
/PR/	CT	Giannella, R. A. et al., "Escherichia coli heat-stable enterotoxins, guanylin, and their receptors: what are they and what do they do?" <i>J. Lab. Clin. Med.</i> (1995), 125(2), 173-181.	
/PR/	CU	Guarino, A. et al., "Small and large intestinal guanylate cyclase activity in children: effect of age and stimulation by Escherichia coli heat-stable enterotoxin," <i>Pediatr. Res.</i> (1987), 21(6), 551-555	
/PR/	CV	Grider J., "Interplay of VIP and nitric oxide in regulation of the descending relaxation phase of peristalsis," <i>Am. J. Physiol.</i> (1993) Feb;264(2 Pt 1):G334-40	
/PR/	CW	Hamra, F. K. et al., "Uroguanylin: structure and activity of a second endogenous peptide that stimulates intestinal guanylate cyclase" <i>Proc. Natl. Acad. Sci. USA</i> (1993), 90(22), 10464-10468.	

Examiner
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	CX	Hawley E. and D. Lane, ANTIBODIES: A Laboratory Manual, Cold Spring Harbor Laboratory, Cold Spring Harbor NY (1988).	
/PR/	CY	Harrison, S. A et al., "Isolation and characterization of bovine cardiac muscle cGMP-inhibited phosphodiesterase: a receptor for new cardiotonic drugs," <i>Mol. Pharmacol.</i> (1986 May);29(5):506-14.	
/PR/	CZ	Hill, O et al., "A new human guanylate cyclase-activating peptide (GCAP-II, uroguanylin): precursor cDNA and colonic expression," <i>Biochim Biophys. Acta</i> (1995) 1253 (2), 146-149.	
/PR/	DA	Hill, D. R et al., "Health advice for international travel," <i>Ann. Intern. Med.</i> (1988), 108(6), 839-852.	
	DB	Hille, B., <i>Ionic Channels of Excitable Membranes</i>, (1984) 1st edition (Sinauer Associates, Sunderland, MA) ISBN 0-87893-322-0.	
/PR/	DC	Hood, J. et al., "Protein kinase G mediates vascular endothelial growth factor-induced Raf-1 activation and proliferation in human endothelial cells," <i>J. Biol. Chem.</i> (1998), 273(36), 23504-23508.	
/PR/	DD	Hughes, J. M. et al., "Role of cyclic GMP in the action of heat-stable enterotoxin of <i>Escherichia coli</i> ," <i>Nature</i> (1978), 271, 755-756.	
/PR/	DE	Kent and Clark-Lewis, <i>Synthetic Peptides in Biology and Medicine</i> , p.295-358 (Alitalo, K et al. Elsevier Science Publishers, Amsterdam, 1985).	
/PR/	DF	Knoop, F. C. et al., "Pharmacologic action of <i>Escherichia coli</i> heat-stable (STa) enterotoxin," <i>J. Pharmacol. Toxicol. Methods</i> (1992) 28(2), 67-72.	
/PR/	DG	Larrick and Fry, "Recombinant antibodies," <i>Hum. Antibod. and hybridomas</i> (1991), 2(4):172-89.	
/PR/	DH	Lucas, K. A. et al., "Guanylyl cyclases and signaling by cyclic GMP," <i>Pharmacol. Rev.</i> (2000), 52(3), 375-414.	

Examiner Signature	/Peter Reddig/	Date Considered	10/06/2007
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 8 of 11

Complete if Known

Application Number	10/775481
Filing Date	February 10, 2004
First Named Inventor	Scott Waldman
Art Unit	1842
Examiner Name	Catherine Joyce
Attorney Docket Number	TJU0016-100 (WAL_SCO.008/CGG)

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	DI	McOmie J.P.W., Protective Groups in Organic Chemistry, Plenum Press, New York, NY (1973)	
/PR/	DJ	Merrifield, "Solid Phase Peptide Synthesis. I. The Synthesis of a Tetrapeptide," <i>J. Am. Chem. Soc.</i> (1963) 15:2149-2154.	
/PR/	DK	Miyazato, M. et al., "Uroguanylin gene expression in the alimentary tract and extra-gastrointestinal tissues," <i>FEBS Lett.</i> (1996), 398 (2-3), 170-174.	
/PR/	DL	Miyazato, M. et al., "Cloning and characterization of a cDNA encoding a precursor for human uroguanylin," <i>Biochem. Biophys Res. Commun.</i> (1996), 219 (2), 644-648.	
/PR/	DM	Miyazato, M. et al., "Genomic structure and chromosomal localization of human uroguanylin," <i>Genomics</i> (1997) 43 (3), 359-365.	
/PR/	DN	Moseley et al., "Isolation and nucleotide sequence determination of a gene encoding a heat-stable enterotoxin of <i>Escherichia coli</i> ," <i>Infect Immun.</i> (1983) 39(3):1167-74.	
/PR/	DO	Notterman, D. A. et al., "Transcriptional gene expression profiles of colorectal adenoma, adenocarcinoma, and normal tissue examined by oligonucleotide arrays," <i>Cancer Res.</i> (2001), 61(7), 3124-3130.	
/PR/	DP	Neurath, H et al., <i>The Proteins</i> , VOL II, 3d Ed., p.105-137,, Academic Press, New York, NY (1976)	
/PR/	DQ	Okamoto, K. et al., "Substitutions of cysteine residues of <i>Escherichia coli</i> heat-stable enterotoxin by oligonucleotide-directed mutagenesis," <i>Infect. Immun.</i> (1985), 55:2121-2125.	
/PR/	DR	Parkinson, S. J. et al., "Interruption of <i>Escherichia coli</i> heat-stable enterotoxin-induced guanylyl cyclase signaling and associated chloride current in human intestinal cells by 2-chloroadenosine," <i>J. Biol. Chem.</i> (1997), 272(2), 754-758.	
/PR/	DS	Penman, I. D. et al., "Dietary calcium supplementation increases apoptosis in the distal murine colonic epithelium," <i>J. Clin. Pathol.</i> (2000), 53(4), 302-307.	

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		Examiner Name	Catherine Joyce
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/PR/	DT	Pitari, G. M. et al., "Guanylyl cyclase C agonists regulate progression through the cell cycle of human colon carcinoma cells," <i>Proc. Natl. Acad. Sci. USA</i> (2001), 98(14), 7846-7851.	
/PR/	DU	Qiu, W. et al., "Cyclic nucleotide-gated cation channels mediate sodium and calcium influx in rat colon," <i>Am. J. Physiol.</i> (2000) 278(2), C336-C343.	
/PR/	DV	Rosado, J. A., "Cyclic nucleotides modulate store-mediated calcium entry through the activation of protein-tyrosine phosphatases and altered actin polymerization in human platelets," <i>J. Biol. Chem.</i> (2001) 276(19), 15666-15675.	
	DW	Sambrook et al., <i>Molecular Cloning: a Laboratory Manual</i> , Second Ed., Cold Spring Harbor Press (1989)	
/PR/	DX	Sauvage F.J. et al., "Primary structure and functional expression of the human receptor for Escherichia coli heat-stable enterotoxin," <i>Journal of Biol. Chemistry</i> (1991) 266(27):17912-8.	
/PR/	DY	Sesink, A. L. et al., "Red meat and colon cancer: dietary haem-induced colonic cytotoxicity and epithelial hyperproliferation are inhibited by calcium," <i>Carcinogenesis</i> (2001) 22(10), 1653-1659.	
/PR/	DZ	Schulz, S. et al., "Guanylyl cyclase is a heat-stable enterotoxin receptor," <i>Cell</i> (1990), 63(5), 941-948.	
/PR/	EA	Shailubhai, K. et al., "Uroguanylin treatment suppresses polyp formation in the Apc(Min/+) mouse and induces apoptosis in human colon adenocarcinoma cells via cyclic GMP," <i>Cancer Res.</i> (2000) 60(18), 5151-5157.	
/PR/	EB	Shimonishi, Y. et al., "Mode of disulfide bond formation of a heat-stable enterotoxin (STh) produced by a human strain of enterotoxigenic Escherichia coli," <i>FEBS Lett.</i> (1987), 215(1):165-170.	
/PR/	EC	So and McCarthy et al., "Nucleotide sequence of the bacterial transposon Tn1681 encoding a heat-stable (ST) toxin and its identification in enterotoxigenic Escherichia coli strains," <i>Proc. Natl. Acad. Sci USA</i> (1980), 77:4011-4015.	

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/PR/	ED	Stern, J. H. et al., "Control of the light-regulated current in rod photoreceptors by cyclic GMP, calcium, and l-cis-diltiazem," <i>Proc. Natl. Acad. Sci. USA</i> (1986) 83(4), 1163-1167.	
	EE	Stuart J. and J.D. Young, <i>Solid-Phase Peptide Synthesis</i> , Pierce Chemical Company, Rockford, IL (1984)	
/PR/	EF	Sugimoto, T. et al., "Atrial natriuretic peptide induces the expression of MKP-1, a mitogen-activated protein kinase phosphatase, in glomerular mesangial cells," <i>J. Biol. Chem.</i> (1996), 271(1), 544-547.	
/PR/	EG	Thompson, W. J. et al., "Exisulind induction of apoptosis involves guanosine 3',5'-cyclic monophosphate phosphodiesterase inhibition, protein kinase G activation, and attenuated beta-catenin," <i>Cancer Res.</i> (2000), 60(13), 3338-3342.	
/PR/	EH	Waldman, S.A. et al., "Influence of a glycine or proline substitution on the functional properties of a 14-amino-acid analog of Escherichia coli heat-stable enterotoxin," <i>Infect. Immun.</i> (1989) 57(8):2420-4.	
/PR/	EI	Vaandrager et al., "Guanosine 3',5'-cyclic monophosphate-dependent protein kinase II mediates heat-stable enterotoxin-provoked chloride secretion in rat intestine," <i>Gastroenterology</i> (1997) 112(2), 437-443.	
/PR/	EJ	Vaandrager et al., "Guanylyl cyclase C is an N-linked glycoprotein receptor that accounts for multiple heat-stable enterotoxin-binding proteins in the intestine," <i>J. Biolog. Chem.</i> (1993) 268(3):2174-2179.	
/PR/	EK	Vaandrager et al., "Differential role of cyclic GMP-dependent protein kinase II in ion transport in murine small intestine and colon," <i>Gastroenterology</i> (2000), 118(1), 108-114.	
/PR/	EL	Waldman, S. A. et al., "Heterogeneity of guanylyl cyclase C expressed by human colorectal cancer cell lines in vitro," <i>Cancer Epidemiol. Biomarkers Prev.</i> (1998) 7(6), 505-514.	
/PR/	EM	Wilmink, A. B. et al., "Overview of the epidemiology of colorectal cancer," <i>Dis. Colon Rectum</i> (1997) 40(4), 483-493	
/PR/	EN	Winter et al., "Man-made antibodies," <i>Nature</i> (1990), 349(6307):293-299.	

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/PR/	EO	Yoshimura, S. et al., "Essential structure for full enterotoxigenic activity of heat-stable enterotoxin produced by enterotoxigenic Escherichia coli" <i>FEBS Lett.</i> (1985) 181(1):138-142	
/PR/	EP	Zufall, F. et al., "Cyclic nucleotide gated channels as regulators of CNS development and plasticity," <i>Curr. Opin. Neurobiol.</i> (1997), 7(3), 404-412.	
/PR/	EQ	Zhang, W. et al., "Interruption of transmembrane signaling as a novel antisecretory strategy to treat enterotoxigenic diarrhea," <i>FASEB J.</i> (1999), 13, 913-922	
/PR/	ER	Zingman, L. V. et al., "Signaling in channel/enzyme multimers: ATPase transitions in SUR module gate ATP-sensitive K ⁺ conductance," <i>Neuron</i> (2001) 31, 233-245.	

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